January 12, 2022

Venus Concept USA Inc.
Nadav Reuben
Senior Director RA & QA
1880 N Commerce Pkwy, Suite 2
Weston, Florida 33326

Re: K213308
Trade/Device Name: Venus BlissMAX
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX, PKT, NGX
Dated: November 14, 2021
Received: November 17, 2021

Dear Nadav Reuben:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Vivek Pinto, PhD
Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213308

Device Name
VENUS BlissMAX DEVICE

Indications for Use *(Describe)*
The Venus BlissMAX device is a diode laser system intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less.

In addition, the Venus BlissMAX device is intended for the treatment of the following medical conditions; using the MP2 applicator for delivery of RF energy combined with massage and magnetic field pulses:
• Relief of minor muscle aches and pain, relief of muscle spasm
• Temporary improvement of local blood circulation
• Temporary reduction in the appearance of cellulite

In addition, The Venus BlissMAX device using the FlexMAX applicators is intended for muscle conditioning to stimulate healthy muscles.
The Venus BlissMAX device using the FlexMAX applicators is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.
The Venus BlissMAX device using the FlexMAX applicators is intended to be operated by a trained professional.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

K213308

VENUS BlissMAX DEVICE

Applicant Name: Venus Concept USA Inc.
1880 N Commerce Pkwy,
Suite 2 Weston, FL33326, USA
Tel: +972-524211666

Contact Person: Nadav Reuben,
Senior Director RA & QA
Venus Concept Ltd.

Date Prepared: January 10, 2022

Common/Usual/Trade Name: Venus BlissMAX device

Regulation Numbers: 21 CFR 878.5400
21 CFR 878.4400
21 CFR 890.5850

Classification Names: Laser For Disruption Of Adipocyte Cells For Aesthetic Use
Massager, Vacuum, Radio Frequency Induced Heat
Stimulator, Muscle, Powered, For Muscle Conditioning

Product Codes: PKT, PBX, NGX

Classification: Class II Medical Device

Classification Panel: Physical Medicine

Predicate Devices: Venus Bliss (K190743)
Body System (K182440)

Reference Devices: InMode System with Tone Applicator (K192249)

Intended Use/Indication for Use:

The Venus BlissMAX device is a diode laser system intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less.

In addition, the Venus BlissMAX device is intended for the treatment of the following medical conditions; using the MP^2 applicator for delivery of RF energy combined with massage and magnetic field pulses:

- Relief of minor muscle aches and pain, relief of muscle spasm
- Temporary improvement of local blood circulation
- Temporary reduction in the appearance of cellulite

In addition, The Venus BlissMAX device using the FlexMAX applicators is intended for muscle conditioning to stimulate healthy muscles.

The Venus BlissMAX device using the FlexMAX applicators is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.

The Venus BlissMAX device using the FlexMAX applicators is intended to be operated by a trained professional.

Device Description:

The Venus BlissMAX device is a computerized system comprised of a system console (main unit), four (4) Diode Laser applicators, one (1) MP^2 (RF+ PEMF+ Vacuum) applicator and four (4) FlexMAX (EMS) applicators. The system delivers laser, bipolar RF and biphasic electrical energies, vacuum pressure, and pulsed electromagnetic fields (PEMF) to the skin and the underlying tissues of the treatment area. The device provides individual adjustment of laser power, EMS intensity level, and RF power, in addition to vacuum levels, for each patient.

The console of the Venus BlissMAX device contains a power supply unit, Laser, RF, and EMS controllers, (power modules, on main board), a suction module (vacuum), a controller unit (on main board), Laser water cooling system (power module, on main board), a touch- screen user interface and display panel.

The applicators are connected to the console via a cable. The RF applicator is comprised of various combinations of RF electrodes, magnetic coils, and vacuum conduits.
The Laser applicators are comprised of a light guide, touch sensors and light-emitting diodes.
The EMS applicator is comprised of two electrodes and a light indicator.

Technological Characteristics:

The Venus BlissMAX device delivers laser energy to the subcutaneous tissue layers via the four diode laser applicators connected to the console. The console utilizes diode laser modules as sources of optical energy and the optical output is fiber-coupled through the applicator to the treatment area. The laser applicators are coupled to the patient's body while using a dedicated belt for the entire treatment. Individual adjustment of the laser output power is provided for each applicator to achieve maximum safety and efficiency for the patient. The laser applicators have an integrated contact skin cooling system to enhance safety and comfort of the treatment.

In addition, the Venus BlissMAX device using the MP^2 applicator provides RF treatments combined with emitted magnetic fields and vacuum massaging. The Vacuum is mainly used for the massaging of deep tissues by creating mild to deep suction. The vacuum massage improves the contact surface between electrodes and tissue. The RF currents heat the adipose and muscular tissues to trigger tissue level changes leading to temporary reduction in the appearance, of cellulite and temporary relief of muscle pain and muscle spasm. The RF heating effect also improves local blood circulation in the sub dermal layers. The PEMF assists in achieving treatment effect.

Furthermore, The Venus BlissMAX device using the FlexMAX applicators (EMS applicators) contracts muscles by passing electrical currents through electrodes contacting the affected body area. The transcutaneous electrical current is designed to effect underlying, healthy muscles, causing them to contract. The FlexMAX applicators are coupled to the patient's body while using a dedicated belt during the entire treatment. The belt size and number of EMS applicators is determined by the treatment area and its size. Its use on muscles is in accordance with a class II device Powered Electrical Muscle Stimulator (Product Code NGX), based on the FDA guidance document for powered muscle stimulators for muscle conditioning as a special control[1].

Performance Data:

Venus Concept conducted several performance tests to demonstrate that the Venus BlissMAX device complies with performance standards and that it functions as intended.

- Performance Bench Testing: Several performance tests were performed, including software validation and device verification tests in order to evaluate the Venus BlissMAX device's outputs per specifications. The results demonstrated that the differences in the technological characteristics of the subject and predicate devices do not raise new types of safety or effectiveness concerns.

[1] The Guidance for Industry, FDA Reviewers/Staff and Compliance Guidance Document for Powered Muscle Stimulator 510(k)s issued on June 9, 1999

- Electrical Safety and Electromagnetic Compatibility: In addition, the device was tested per the applicable electrical safety and electromagnetic compatibility standards listed below, and all results were passing.
    - IEC 60601-1:2005+ Amd.1: 2012, Ed.3.1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
    - IEC 60601-2-2 :2017 Ed. 6 Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
    - IEC 60601-1-6: 2010+ Amd.1:2013 Ed.3.1, General requirements for basic safety and essential performance - Collateral standard: Usability
    - IEC 60601-2-10:2012+Amd.1:2016, Ed. 2.1, Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
    - IEC 60601-1-2:2014 Ed. 4, General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
    - IEC 60825-1:2014 Ed.3, Safety of laser products - Part 1: Equipment classification and requirements
    - IEC 60601-2-22:2007+Amd.1:2012 Ed. 3.1 Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
    - IEC 62304:2006+Amd.1:2015 Ed.1.1, Medical device software – Software life cycle processes

- Software Testing: The software was also subjected to verification and validation testing, and results demonstrated that the system performed as intended.

These performance tests demonstrated that the device meets the system requirements and do not raise new types of safety or effectiveness concerns.

Substantial Equivalence:

The following tables compare the Venus BlissMAX device to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

Venus Concept, Ltd.'s Venus BlissMAX Substantial Equivalence Tables

Table 1: Substantial Equivalence Table for the Diode Laser Applicators:

	Proposed Device: Venus BlissMAX Venus Concept Ltd.	**Predicate Device: Venus Bliss Venus Concept Ltd. (K190743)**	**Substantial Equivalence Discussion**
Classification Product Code, Regulation	Class II, PKT, 21 CFR 878.5400	Class II, PKT, 21 CFR 878.5400	Same
Indications for Use	The Venus BlissMAX device is a diode laser system intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less.	The Venus Bliss device is a diode laser system intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less.	Same
Lipolysis Method	Heat-assisted	Heat-assisted	Same
Energy Used / Delivered	Diode Laser	Diode Laser	Same
Components	System Console (with graphical user interface) 4 Applicators - Sapphire light guides - LED contact sensors	System Console (with graphical user interface) 4 Applicators - Sapphire light guides - LED contact sensors	Same
Wavelength	1064 ± 10nm (infrared)	1064 ± 10nm (infrared)	Same
Spot Size	6 x 6 cm^2 on each of the Applicator heads	6 x 6 cm^2 on each of the Applicator heads	Same
Operation Mode	CW	CW	Same

	Proposed Device: Venus BlissMAX Venus Concept Ltd.	Predicate Device: Venus Bliss Venus Concept Ltd. (K190743)	Substantial Equivalence Discussion
Power Density	Up to 1.4 W/cm^2	Up to 1.4 W/cm^2	Same
Attachment to Patient	Belt	Belt	Same
Electrical Power	100-240V~50/60 Hz, Single Phase	100-240V~50/60 Hz, Single Phase	Same
Cooling system	Distilled water or Venus Concept Chiller Fluid	Distilled water or Venus Concept Chiller Fluid	Same
Materials	Biocompatible	Biocompatible	Same
Sterility	Non-sterile	Non-sterile	Same

Table 2: Substantial Equivalence Table for the MP^2 (RF+ PEMF +Vacuum) Applicators:

	Proposed Device: Venus BlissMAX Venus Concept Ltd.	Predicate Device: Venus Bliss Venus Concept Ltd. (K190743)	Substantial Equivalence Discussion
Classification, Product Code, Regulation	Class II, PBX, 21 CFR 878.4400	Class II, PBX, 21 CFR 878.4400	Same
Indications for Use	The Venus BlissMAX device is intended for the treatment of the following medical conditions; using the MP^2 applicator for delivery of RF energy combined with massage and magnetic field pulses: • Relief of minor muscle aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation • Temporary reduction in the appearance of cellulite.	The Venus Bliss device is intended for the treatment of the following medical conditions; using the MP^2 applicator for delivery of RF energy combined with massage and magnetic field pulses: • Relief of minor muscle aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation • Temporary reduction in the appearance of cellulite.	Same

	Proposed Device: Venus BlissMAX Venus Concept Ltd.	Predicate Device: Venus Bliss Venus Concept Ltd. (K190743)	Substantial Equivalence Discussion
Energy Used / Delivered	1. RF Energy 2. Pulsed Electromagnetic Field (PEMF) 3. Vacuum	1. RF Energy 2. Pulsed Electromagnetic Field (PEMF) 3. Vacuum	Same
Design	Use of RF and PEMF energies delivered through applicator with vacuum and massage of the skin.	Use of RF and PEMF energies delivered through applicator with vacuum and massage of the skin.	Same
Components	Console, including: -Power supply -RF generator -Suction Module -Main CPU -Display panel -PEMF generator Applicator: -MP^2	Console, including: -Power supply -RF generator -Suction Module -Main CPU -Display panel -PEMF generator Applicator: - MP^2	Same
Applicators	- MP^2 applicator: comprised of 12 RF electrodes (8 peripheral and 4 internal), 8 PEMF coils covering the 8 peripheral RF electrodes, vacuum conduits	- MP^2 applicator: comprised of 12 RF electrodes (8 peripheral and 4 internal), 8 PEMF coils covering the 8 peripheral RF electrodes, vacuum conduits	Same
Device Dimensions	21.7x25.6x53.2 in 55x65x135 cm	21.7x25.6x53.2 in 55x65x135 cm	Same
Applicator Footprint Dimensions	MP^2: 38.5 cm^2	MP^2: 38.5 cm^2	Same
Performance	Frequency: 1MHz Vacuum pressure: -400mbar Maximal RF output power: 100W PEMF Power: 15 Gauss (15Hz)	Frequency: 1MHz Vacuum pressure: -400mbar Maximal RF output power: 100W PEMF Power: 15 Gauss (15Hz)	Same
Materials	Biocompatible	Biocompatible	Same
Sterility	Non-sterile	Non-sterile	Same
Power requirements	100-120 VAC / 60Hz 220-240 VAC / 50Hz	100-120 VAC / 60Hz 220-240 VAC / 50Hz	Same

Table 3: Substantial Equivalence Table for the FlexMAX (EMS) Applicators:

	Proposed Device: **Venus BlissMAX** **Venus Concept Ltd.**	**Predicate Device:** **Body System** **A-1 Engineering** **(K182440)**	**Reference Device:** **InMode System with Tone Applicator** **InMode Ltd.** **(K192249)**	**Substantial Equivalence Discussion**
Basic Unit Characteristics				
Classification Product Code, Regulation	Class II, NGX, 21 CFR 890.5850	Class II, NGX, 21 CFR 890.5850	Class II, IPF & GZJ, 21 CFR 890.5850 & 882.5890	Same as the Predicate device
Indications for Use	The Venus BlissMAX device using the FlexMAX applicators is intended for muscle conditioning to stimulate healthy muscles. The Venus BlissMAX device using the FlexMAX applicators is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. The Venus BlissMAX device using the FlexMAX applicators is intended to be operated by a trained professional.	The Body System is intended for muscle conditioning to stimulate healthy muscles. The Body System is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. The Body System is intended to be operated by a trained professional who is present to monitor treatment.	The InMode System with Tone Applicator is used in EMS mode for: - Prevention or retardation of disuse atrophy - Maintaining or increasing range of motion -Muscle re-education - Relaxation of muscle spasms - Increasing local blood circulation - Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis And in TENS mode for: - Symptomatic relief and management of chronic, intractable pain - Post-surgical acute pain - Post-traumatic acute pain	Same as the Predicate device
Components	The Venus BlissMAX device consists of the following components: • Console, including a power supply unit, controller and user interface including an LCD touch screen.	The body System is a Powered Muscle Stimulator with 16 channel ports using self-adhesive pad applicators attached to the body for muscle conditioning.	The InMode System consists of the following components: • Console, including a power supply unit, controller and user interface including an LCD touch screen.	Similar to the Reference device

	Proposed Device: Venus BlissMAX Venus Concept Ltd.	Predicate Device: Body System A-1 Engineering (K182440)	Reference Device: InMode System with Tone Applicator InMode Ltd. (K192249)	Substantial Equivalence Discussion
	• Several types of applicators for different indications (Laser, MP^2, FlexMAX applicators) connected to the console via a cable.		• Tone Applicator connected to the console via a cable.	
Mechanism of Action	Muscle contraction by electrical pulsing.	Muscle contraction by electrical pulsing.	Muscle contraction by electrical pulsing.	Same as the Predicate and Reference devices
Power Source	Main Line Frequency (nominal): 50-60Hz Input Voltage (nominal): 100-240VAC	Main Line Frequency (nominal): 50-60Hz Input Voltage (nominal): 110-240VAC	Main Line Frequency (nominal) 50-60Hz Input Voltage (nominal) 100-240VAC	Similar
Method of Line Current Isolation	Power Supply isolation	Power Supply isolation	Independent transformer isolated	Same as the Predicate device
Patient Leakage Current	Normal condition: 1 µA Single Fault condition: 11 µA	Normal condition: 0.05 µA Single Fault condition: 0.05 µA	Normal condition: <100 µA Single Fault condition: <300 µA	Similar Complies with the FDA Guidance on Powered Muscle Stimulators and IEC 60601-2-10 standard Normal condition: <100 µA patient leakage Single Fault condition: <500 µA line leakage
Number of Output Modes	1	5	2	Different The subject, predicate and reference devices have a similar output mode with symmetrical biphasic pulses that meets the requirements of the FDA Guidance for Powered Muscle Stimulators.
Number of Output Channels	4	16	2	Different All channels for the subject, predicate and

	Proposed Device: Venus BlissMAX Venus Concept Ltd.	Predicate Device: Body System A-1 Engineering (K182440)	Reference Device: InMode System with Tone Applicator InMode Ltd. (K192249)	Substantial Equivalence Discussion
				reference devices are isolated from each other and generate an output with identical essential parameters.
Channel Output: Synchronous or Alternating	Synchronous	Synchronous	Not available	Same as the Predicate device
Method of channel isolation	Isolation transformer per channel	Not available	Through transformers and isolators	Similar
Regulated Current or Regulated Voltage	Regulated voltage with current limit	Both	Regulated voltage on all channels with current limit	Same as the Predicate and Reference devices (voltage regulated devices)
Software/ Firmware/ Microprocessor Control	Yes	No	Yes	Similar to the Reference device
Automatic Overload Trip	No	Yes	Yes	Different
Automatic No load Trip	No	Yes	Yes	Different
Automatic EMS Shut off	Yes- Automatic EMS treatment shut off	Not available	Yes, On/off switch	Similar to the reference device
Patient Override Control	Yes- Emergency button	Not available	Yes	Similar to the reference device
Indicator Display: On / Off Status	Yes	Yes	Yes	Same as the Predicate and Reference devices
Indicator Display: Low Battery	No Battery	Not available	No battery	Similar
Indicator Display: Voltage Current Level	Yes	Yes	Yes	Same as the Predicate and Reference devices

	Proposed Device: Venus BlissMAX Venus Concept Ltd.	Predicate Device: Body System A-1 Engineering (K182440)	Reference Device: InMode System with Tone Applicator InMode Ltd. (K192249)	Substantial Equivalence Discussion
Timer Range	Selectable 15, 30, 45, 60 min	None	0-60 [minutes]	Similar to the Reference device
Compliance with Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-6 IEC 62304 ISO 10993-1 ISO 14971	Electrical Safety and EMC: IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 Biocompatibility: ISO10993-5 ISO10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-6 ISO 10993-1	Similar
Compliance with 21 CFR 898	Yes	Yes	Not available	Similar
Weight	62 Kg / 136.7 lbs	Not available	20.0 Kg [44 lbs]	Different
Dimensions	21.7 x 25.6 x 53.2 in 55 x 65 x 135 cm	Not available	35cm W x 35cm D x 100cm H [18.2'' W x 18.2'' D x 40'' H]	Different
Housing Materials and Construction	Biocompatible	Biocompatible	Biocompatible	Similar
Output Specifications				
Waveform	Symmetrical Biphasic waveform	Symmetrical Biphasic waveform	Symmetrical Biphasic waveform	Same as the Predicate and Reference devices

	Proposed Device: Venus BlissMAX Venus Concept Ltd.	Predicate Device: Body System A-1 Engineering (K182440)	Reference Device: InMode System with Tone Applicator InMode Ltd. (K192249)	Substantial Equivalence Discussion
Shape	Rectangular	Rectangular	Rectangular	Same as the Predicate and Reference devices
Maximum Output Voltage	40V@500Ω 105V@2kΩ 160V@10kΩ	58V @ 500 Ω 88V @ 2k Ω	56V @500Ω 56V @2 kΩ 56V @10kΩ	Similar
Maximum Output Current	80 mA @ 500 Ω 52.5 mA @ 2 kΩ 16 mA @ 10 kΩ	108 mA at 500 Ω	112 mA @ 500 Ω 28 mA @ 2 kΩ 5.6 mA @ 10 kΩ	Similar
Frequency range	1 Hz to 1000 Hz	200 to 1200 Hz	3 to 200 Hz	Similar
Pulse width range	500 to 2500 [µs]	500 to 2500 [µs]	20 to 400 [µs]	Same as the Predicate device
Net Charge	0 [µC] @ 500Ω Zero net charge is achieved by using symmetrical biphasic waveforms	0 @ 500 Ω Zero net charge is achieved by using symmetrical biphasic waveforms	0 [µC] @ 500Ω	Same as the Predicate and Reference devices
Maximum Phase Charge	40 [µC] @ 500Ω @ 1000 Hz	45 µC @ 500 Ω @ 200 Hz	44.8 [µC] @ 500Ω	Similar
Maximum Current Density	2.5 mA/cm^2	5 mA/cm^2	1 mA/cm^2	Similar The Venus BlissMAX device's maximum current density is encompassed within those of the Predicate and Reference devices.
Maximum Power Density	55 [mW/cm^2] @500Ω	0.011 W/cm^2 (11 mW/ cm^2)	55 [mW/cm^2] @500Ω	Same as the Reference device
Burst Mode (i.e., pulse trains) **a. Pulses per burst**	N/A- No Burst Mode	Not available	Yes: a. 3 - 200 b. 1	Different

	Proposed Device: Venus BlissMAX Venus Concept Ltd.	Predicate Device: Body System A-1 Engineering (K182440)	Reference Device: InMode System with Tone Applicator InMode Ltd. (K192249)	Substantial Equivalence Discussion
b. Bursts per second **c. Burst duration (sec)** **Duty Cycle [Line(b)xLine (c)]**			c. 1-60 sec d. Time on / off	
On Time (sec)	N/A- No Burst Mode	Not available	1 – 60 [sec]	Different
Off time (sec)	N/A- No Burst Mode	Not available	1 – 60 [sec]	Different

As described in the comparison tables above, the Venus BlissMAX device has the same intended use and indications for use, similar technological characteristics, and principles of operation as its predicate devices. The technological differences between the Venus BlissMAX device and its predicate and reference devices do not raise any new issues of safety or effectiveness. The Venus BlissMAX device and its predicate devices Venus Concept's Venus Bliss (K190743), A-1 Engineering's Body System (K182440) and its reference device the InMode System with Tone Applicator (K192249) are based on the same core technology of RF along with PEMF and vacuum massaging (as in the Venus Bliss), Diode Laser (as in the Venus Bliss) and EMS (as in the Body System and the InMode System with Tone Applicator), for the same indications for use. The design and components in the Venus BlissMAX device, including the console and the applicators are similar to the design and components found in the predicates and the reference device. The technological differences do not alter the device's core technology or performance.

Furthermore, the Venus BlissMAX device underwent performance testing, including software validation testing, electrical safety and electromagnetic compatibility testing. These performance tests in addition to the bench test demonstrated that the differences in the technological characteristics between the subject's predicate and reference device do not raise new types of safety or effectiveness concerns.

Conclusions:

Therefore, based on the same intended use and indications for use, similar technological characteristics, and principles of operation, the Venus BlissMAX device is substantially equivalent to its predicate devices, the Venus Bliss (K190743) and the Body System (K182440).